

## REMARKS

This paper is in direct response to the Office Action dated March 12, 2004 in which the Examiner stated that Applicant's Amendment dated November 4, 2003 was non-responsive. The courtesy of the Examiner in allowing Applicant to submit a complete response is appreciated. Accordingly, this paper includes the arguments and claims presented in Applicant's November 2003 Amendment and additional arguments and amendments as requested in the March 2004 Office Action.

Claims 25-63 were pending and examined in the Office Action dated August 4, 2003. Claim 43 was allowed, claims 25-37, 39 and 44-63 were rejected, and claims 38, 40-42 were objected to in that Office Action. Claims 30, 33 and 39 have been modified and claims 64-67 have been added by this Amendment. Accordingly, claims 25-67 are now pending in this application. Applicant believes that no new matter has been added by this Amendment. Applicant respectfully requests reconsideration of the above-referenced application.

## REJECTIONS UNDER 35 U.S.C. § 112

Claims 30, 33 and 39 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In the August 2003 Office Action, the Examiner asked: "what does 'composites' mean?", "what does 'swaged' mean?" and "what does 'to sinter grains of the medical device together' mean?" In response to the Examiner's questions, Applicant has attached hereto, by way of example and not meant to be limiting, pages 86, 87, 421, 470 from the American Society for Metals' (ASM) Materials Engineering Dictionary (1st ed., 1992) containing representative definitions for the terms "composite material," "swage" and "sinter."

Furthermore, Applicant has used the terms "composite," "swage" and "sinter" throughout the specification. Applicant notes that the Examiner has not objected to the

specification under 35 U.S.C. § 112, first paragraph. Therefore, Applicant respectfully submits that the meaning of those claim terms would be known to one of ordinary skill in the art of coating medical devices in view of the context of Applicant's specification. In addition, Applicant has amended claims 30, 33 and 39 to clarify the claims as requested by the Examiner. Accordingly, Applicant respectfully requests that the rejections under § 112, second paragraph be withdrawn.

### **REJECTIONS UNDER 35 U.S.C. § 102**

Claims 25, 29, 31 and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Schwartz et al. (US 6,368,658). Applicant respectfully traverses these rejections. In order to maintain a rejection under § 102, the Office must show that each and every element of Applicant's claimed invention is disclosed in the cited reference. Applicant submits that Schwartz '658 does not teach or suggest using a thermal spray process to coat a medical device as recited in Applicant's claim 25, namely, cold spray, combustion, hvof, arc, and plasma spray processes.

Foremost, the apparatuses shown in the figures of Schwartz '658 are incompatible with a thermal spray process. Merely because a reference discloses a coating process does not mean that it is a "thermal spray process" as disclosed and claimed by Applicant. By way of illustration and not meant to be limiting, page 321 from the ASM Materials Engineering Dictionary is provided and contains a definition and a schematic of a conventional plasma spray process.

The "plasma coating" discussion at col. 11, lines 3-36 does not teach a plasma spray process as disclosed (FIG. 13) and claimed by Applicant. The plasma coater 305 disclosed in Schwartz '658 suspends the medical devices 300 within a chamber 120. Although the coating material may be introduced through airstreams 161, 140, Schwartz '658 does not disclose a thermal spray process wherein the molten or heat softened

coating material is directed at a high velocity onto the medical device. Instead, a plasma deposition process is taught by Schwartz `658 to apply the coating to the medical devices. In addition, the other coating processes in Schwartz `658 that were referenced by the Examiner are not thermal spray processes as claimed by Applicant. Thus, Applicant respectfully submits that the Examiner's rejection of claims 25, 29, 31 and 37 under § 102 should be withdrawn.

### REJECTIONS UNDER 35 U.S.C. § 103

#### CLAIMS 25, 26, 28-31, 36, 44-59, 61 and 63

Claims 25-26, 28-31, 36, 44-59, 61 and 63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schwartz `658 in view of Chow et al. (US 6,447,848). Applicant respectfully traverses these rejections, and disagrees with several of the assertions in the Office Action (not all disagreements are addressed in this response). As discussed herein regarding the § 102 rejections, Schwartz `658 does not teach a thermal spray process, but a deposition process in which the medical device to be coated are suspended in an air stream. Thus, the Examiner's statement that Schwartz `658 and Chow `848 are analogous "because they are both deal with spray coating techniques" is erroneous. Accordingly, there is no suggestion or motivation to use the liquid solution materials of Chow `848 proposed for use in "thermal spraying" (col. 2, line 18) in the deposition process of Schwartz `658.

Moreover, Applicant submits the apparatuses of Schwartz `658 are incompatible with the thermal spray process of Chow `848, which requires the use of a flame. Introduction of a flame into the spray chamber of Schwartz `658 would damage the circulating medical devices, and there is no teaching in either reference as to how to modify the chamber of Schwartz `658 to accommodate the flame and associated high temperatures. Thus, Applicant respectfully submits that the Examiner's rejection of claims 25-26, 28-31, 36, 44-59, 61 and 63 under § 103 should be withdrawn.

**CLAIMS 25-27, 31-32 and 34-37**

Claims 25-27, 31-32 and 34-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Helmus et al. (US 2002/0032477) in view of the article by Herman et al. "Thermal Spray: Current Status and Future Trends" (MRS Bulletin, July 2000, pp. 17-25). Applicant respectfully traverses these rejections, and disagrees with several of the assertions in the Office Action (not all disagreements are addressed in this response). The Examiner acknowledges that Helmus '477 does not teach a thermal spray process as claimed by Applicant. Even if modifying the Helmus '477 medical device with the disclosure of Herman did teach Applicant's claimed thermal spray process, which it would not, there is no teaching or even the faintest suggestion to combine the references.

To support an obviousness rejection there must be some suggestion or motivation to modify a reference or combine reference teachings -- see MPEP § 706.02(j). As the Examiner apparently appreciates, there is no teaching or suggestion in Helmus '477 to use a thermal spray process to coat a stent or other medical device. Applicant respectfully submits that Herman's reference to "nonthermal" methods does nothing to provide motivation for one having ordinary skill in the art to "employ the processes of Herman when making the coated stents of Helmus." Herman et al. merely state that known spray coating methods may be nonthermal, e.g., cold spray that supersonically propels ductile metals onto a substrate (col. 1, third paragraph). That statement does not teach or suggest using a thermal spray process as disclosed and claimed by Applicant to coat a medical device, such as a stent. Thus, there is no motivation found in Herman for one of ordinary skill in the art to use a thermal spray process to coat a medical device. Without such a teaching or suggestion to combine the references, the Examiner is using improper hindsight to glean from Applicant's teachings that which is not disclosed in the prior art. See In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Thus, Applicant respectfully submits that the Examiner's rejection of claims 25-27, 31-32 and 34-37 under § 103 should be withdrawn.

### CLAIMS 25, 28 and 61-62

Claims 25, 28 and 61-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the article by Herman in view of Simm et al. (US 4,681,734). Applicant respectfully traverses these rejections, and disagrees with several of the assertions in the Office Action (not all disagreements are addressed in this response). Applicant respectfully submits that the Examiner has not properly carried the Office's burden under § 103, as outlined in Sections 11 and 13 of the August 2003 Office Action so as to allow Applicant to provide a meaningful response -- see MPEP § 706.02(j).

The Examiner's argument in Section 15 of the August 2003 Office Action merely addresses the failure of Herman to teach coatings having certain grain sizes as claimed by Applicant (claims 61, 62). The rejection says nothing relevant regarding Applicant's claims 25 and 28. Applicant respectfully submits that it is the burden of the Examiner, not Applicant, to apply the elements of Graham, namely to point out the differences between the applied references and the features of each of Applicant's claims -- see MPEP § 2141.

Furthermore, the Examiner acknowledges that Herman does not teach the grain sizes in the applied coatings as recited in Applicant's claims 61 and 62. The Simm '734 thin specification merely teaches the use of certain grain sizes in the feedstock powder used to form the coatings (see, e.g., col. 1, lines 43-47, 53-54). Simm '734 does not teach particular grain sizes of a metal alloy coating formed on a medical device by a cold spray process as claimed by Applicant.

Even if modifying the spray process of Herman with the disclosure of Simm '734 did teach Applicant's claimed invention, which it would not, there is no teaching or suggestion to combine the references. The abstract of Simm '734 regarding "resistance to pulling by traction" (bond strength) is not relevant motivation. Such a functional characteristic of the applied coating says nothing to one of ordinary skill in the art as to what method to use to make such a coating. Thus, one having ordinary skill in the art

would not learn from Simm '734 how to modify the methods disclosed in Herman so as to possess Applicant's claimed invention. Accordingly, Applicant respectfully submits that the Examiner's rejection of claims 25, 28 and 61-62 under § 103 should be withdrawn.

### **CLAIMS 60 and 63**

Dependent claims 60 and 63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the article by Herman in view of Simm '734 and further in view of Schwartz '658. Applicant respectfully traverses these rejections, and disagrees with several of the assertions in the Office Action (not all disagreements are addressed in this response). As discussed herein regarding Applicant's independent claim 61, the combination of Herman and Simm '734 does not teach coating a medical device with a cold spray process as recited in Applicant's claims. The Examiner has not applied Herman and Simm '734 to Applicant's independent claim 58. Since Schwartz '658 merely discusses stents as a target for its deposition process, that reference adds nothing to overcome the deficiencies of Herman and Simm '734 to teach Applicant's claimed invention as a whole.

As discussed herein, the Examiner's allegations of motivation to combine the teachings of the applied references are inadequate to carry the Office's burden to establish a *prima facie* case of obviousness -- see MPEP § 2143.01. The Examiner has used non-relevant statements in the references to justify the applied combination. For example, Simm's reference to an improved resistance to pulling is not sufficient to those of ordinary skill in the art to modify the spray methods of Herman to provide a coating having a variable thickness (claim 60) or to provide a grain size of less than thirty-two microns (claim 63). Similarly, it does not follow whatsoever that those of ordinary skill in the art would modify Herman to coat medical devices, such as Schwartz' stents, merely because Herman itself mentions that a cold spray process is nonthermal. Thus, Applicant

respectfully submits that the Examiner's rejection of claims 60 and 63 under § 103 should be withdrawn.

### **CLAIM 39**

Dependent claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Noiles et al. (US 5,358,533) in view of the article by Herman. Applicant respectfully traverses this rejection, and disagrees with several of the assertions in the Office Action (not all disagreements are addressed in this response). Additionally, Applicant has modified claim 39 to add clarity to the claim. As the Examiner acknowledges, Noiles '533 does not teach using a thermal spray process to form a coating on a medical device as recited in Applicant's independent claim 25. Furthermore, Noiles '533 teaches using conventional sintering techniques to apply the coating at high temperatures (col. 3, lines 5-10), and does not teach the post-coating high pressure sintering process recited in Applicant's claim 39. The disclosure of Herman is insufficient to overcome those deficiencies in the teachings of Noiles '533.

Even if modifying the Noiles '533 sintered implantable prostheses with the disclosure of Herman did teach Applicant's claimed thermal spray process, which it would not, there is no suggestion to combine the references. Again, the Examiner's allegation of motivation to combine the applied references is inadequate to carry the Office's burden under § 103. Herman's disclosure that a cold spray process is nonthermal is not a sufficient or even a relevant teaching to those of ordinary skill in the art to use the high temperature sinterable materials of Noiles '533 in the spray processes disclosed by Herman. Thus, Applicant respectfully submits that the Examiner's rejection of claim 39 under § 103 should be withdrawn.

## CONCLUSION

Applicant has added new claims 64-67 in view of the Examiner's objection to claims 38 and 40-42. The relevant limitations of claim 38 and 25 have been incorporated into claim 64. Using claim 25 as the base claim, the relevant limitations of claims 40-42 have been incorporated into claims 65-67, respectively. Accordingly, Applicant respectfully submits that claims 64-67 are allowable.

Additionally, Applicant submits a Supplemental Information Disclosure Statement, filed concurrently herewith.

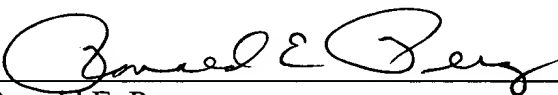
In view of the above amendments and remarks, Applicant respectfully submits that claims 25-67 are in condition for allowance, and that the application should be passed to issue. The Examiner is encouraged to contact the undersigned should there be any questions or resolvable matters regarding this application.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

Dated: 12 APR 04

By:



Ronald E. Perez

Registration No. 36,891

Enclosure: ASM Materials Engineering Dictionary  
pgs. 86, 87, 421, 470

Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696  
Customer No. 24201

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